K001525

Summary of Safety and Effectiveness Information
Captia™ Syphilis-G ELISA Test Kit

NOV 2 9 2000

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II. Description of Device

CAPTIA™ Syphilis-G is an enzyme immunoassay for the qualitative presumptive detection of IgG antibodies to *Treponema pallidum* in:
(i) serum specimens, as a clinical lab test for antibodies to *T. pallidum*. The CAPTIA™ Syphilis-G is a treponemal assay, therefore patients with previously treated syphilis will be positive on the assay. The test can not distinguish between present and past infection. Any sera giving reactive or equivocal results on initial testing must be supplemented with a quantitative nontreponemal test (such as RPR and VDRL) to distinguish active disease and assist in ruling out false positives. or,
(ii) serum or plasma specimens for use in the primary screening of blood and/or plasma donations; or,
(iii) serum specimens, as a confirmatory test to distinguish true reactive from false reactive non-treponemal test results that may be obtained when individuals are initially screened for syphilis.

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Microtitration wells coated with *T. pallidum* antigens are exposed to test specimens which may contain specific antibodies. After an incubation period, unbound components in the test sample are washed away. Specifically-bound IgG reacts with a biotinylated anti-human IgG monoclonal antibody bound with streptavidin-horseradish peroxidase (HRP) during a second incubation period. Following a second wash cycle, specifically-bound enzyme conjugate is detected by reaction with hydrogen peroxide and the chromogen tetramethylbenzidine (TMB). The assay is measured spectro-photometrically to indicate the presence or absence of IgG treponemal antibodies.

III. Predicate Device

The CAPTIA™ Syphilis-G ELISA test is substantially equivalent to RPR serology. Equivalence is demonstrated by the following comparative results:

Performance Characteristics

Primary Screening Test Application

Comparison with other serological tests

CAPTIA™ Syphilis-G has been evaluated at a number of independent clinical laboratories. Serum specimens routinely referred for syphilis serology were analysed by CAPTIA™ Syphilis-G in parallel with haemagglutination (MHA-TP) and VDRL tests. Specimens giving reactive results by any test were further tested by the FTA-ABS procedure. The tables below summarize results from initial testing at two trial centers. In all cases a reactive is defined as a serum specimen which gives a reactive result by either the MHA-TP or VDRL test and which is confirmed by the FTA-ABS test.

Trial I

Total 1321 Specimens

	CAPTIA™ SYPHILIS-G		MHA-TP		VDRL	
T. pallidum antibody status	R	N	R	N	R	N
Reactive	60	1[d]	60	1[a]	25	36[c]
Non-reactive	9[b]	1251	6[c]	1254	12	1248
Relative Sensitivity	98.4%		98.4%		N/A	
Relative Specificity	99.3%		99.5%		N/A	

Note: Equivocals scored as reactive.

[a] Confirmed untreated primary infection, reactive by CAPTIA™ Syphilis-G.

[b] Includes 7 specimens in equivocal range.

[c] On repeat testing confirmed as non-specific agglutination, therefore are inconclusive.

[d] Weakly reactive case of treated latent syphilis.

[e] The proportion of this specimen group representing cases of successfully treated syphilis, which would not normally be VDRL reactive, is not known.

Trial 2

Total 177-179 Specimens

	CAPTIA™ SYPHILIS-G		MHA-TP		VDRL	
T. pallidum antibody status	R	N	R	N	R	N
Reactive	76	0	76	0	25	49[b]
Non-reactive	0	103	3[a]	100	0	103
Relative Sensitivity	100%		100%		N/A	
Relative Specificity	100%		97.1%		N/A	

Note: Equivocals scored as reactive.

[a] Includes 2 serum specimens which, on repeat testing, were confirmed as causing non-specific agglutination, therefore are inconclusive.

[b] The proportion of this specimen group representing cases of successfully treated syphilis, which would not normally be VDRL reactive, is not known.

Trial 3

Reaction with serum specimens classified according to stage of disease.

The following table summarizes CAPTIA™ Syphilis-G results using serum specimens taken from patients at various stages of the disease and following treatment. Diagnosis was based on clinical history together with serological data from VDRL and FTA-ABS tests. (3)

Syphilis Category	Number of Speciment	Number Reactive by Test		
		CAPTIA™ Syphilis-G	VDRL	FTA-ABS
Untreated				
Primary	17	14	16	17
Secondary	13	13	13	13
Early Latent	14	14	12	14
Late Latent	33	33	17	33
Neurosyphilis	3	3	3	3
Congenital	1	1	1	1
Reinfection	15	15	15	15
Treated				
Uncharacterized	72	72	46	Data Not Available
Total:	168			
Sensitivity:		165/168 = 98.2%	77/96 = 80.2%	96/96 = 100%

*Calculated from untreated cases only

Trial 4

The Centers For Disease Control and Prevention analysed serum samples from a high risk population using CAPTIA™ Syphilis-G, the RPR and FTA-ABS tests. Serum samples were from patients with primary, secondary or latent infections and patients with no history of syphilis known to give false reactive reactions in nontreponemal tests.

	RPR		FTA-ABS		CAPTIA™ Syphilis G	
STAGE	R	N	R	N	R	N
PRIMARY						
untreated	4	1	5	0	5	0
treated	5	0	5	0	5	0
SECONDARY						
untreated	3	0	3	0	3	0
treated	3	0	3	0	3	0
LATENT						
untreated	4	0	4	0	4	0
treated	9	2	11	0	11	0
NONSYPHILIS*	12	6	0	18	1	17

* These serum samples were obtained from individuals without syphilis, but who had diseases known to cause false reactive results in the nontreponemal tests.

Sensitivity:	RPR	FTA-ABS	CAPTIA™ Syphilis-G
untreated	11/12=92%	12/12=100%	12/12=100%
treated	17/19=90%	19/19=100%	19/19=100%
overall	28/31=90%	31/31=100%	31/31=100%
Specificity	Inappropriate	18/18=100%	17/18=94%
Agreement of CAPTIA™ Syphilis-G with FTA-ABS: 48/49= 97.96% Agreement of RPR with FTA-ABS 40/49= 81.63%			

Trial 5

Comparison with the RPR test

585 serum specimens routinely submitted to a clinical serology laboratory, were tested by RPR and CAPTIA™ Syphilis-G. Serum specimens yielding reactive or equivocal results by either method were further tested by the FTA-ABS procedure.

Of the 585 specimens tested, only 69 were initially reactive, and then tested in the FTA-ABS procedure. The remaining 516 serum specimens were non-reactive in both the RPR test and CAPTIA™ Syphilis-G.

RPR Card	CAPTIA™ Syphilis G	FTA-ABS	Number with Pattern
N	N	N	7
N	R	R	15
R	R	R	37
N	R	N	3
N	E	R	2
N	E	N	1
N	N	R	1
R	N	N	3
N=non-reactive		R=reactive	E=Equivocal

Agreement between CAPTIA™ Syphilis-G and the FTA -ABS test results

	CAPTIA™ Syphilis-G Reactive	CAPTIA™ Syphilis-G Non-reactive
FTA-ABS Reactive	54	1
FTA-ABS Non-reactive	4	10
Equivocal results scored as reactive. Agreement = 64/69 or 92.7%		

Trial 6

Clinical Sensitivity

A panel of frozen retrospective characterized sera obtained from the CDC (Centers for Disease Control) were assayed on the Captia Syphilis G by Trinity Biotech. The panel consists of 100 sera with clinical diagnosis of Syphilis with different stages of disease. Treated and untreated patients are included in each disease stage. The following table illustrates the performance of the assay with the serum panel. The data is presented for information on the assay with a characterized serum panel and does not infer an endorsement of the assay by the CDC.

Results of the CDC Serum Panel on the Captia Syphilis G

Disease Stage	+	E	-	Total	% Positive
Primary Treated	15	0	1	16	93.8%
Primary Untreated	8	0	0	8	100%
Secondary Treated	27	0	0	27	100%
Secondary Untreated	21	0	1	22	95.5%
Late Treated	20	0	1	21	95.2%
Late Untreated	6	0	0	6	100%
Total	97	0	3	100	97%

Trial 7

Clinical Sensitivity

A panel of frozen retrospective characterized sera were assayed on the Captia Syphilis G by a public health laboratory in the United Kingdom. The panel consists of 200 sera with clinical diagnosis of Syphilis with different stages of disease. Treated and untreated patients are included in each disease stage. The following table illustrates the performance of the assay with the serum panel.

Results of the characterized Serum Panel on the Captia Syphilis G

Disease Stage	+	E	-	Total	% Positive
Primary Treated	5	0	0	5	100%
Primary Untreated	19	1	0	20	95%
Secondary Treated	27	1	1	29	93.1%
Secondary Untreated	23	0	0	23	100%
Late Treated	29	0	1	30	96.7%
Late Untreated	92	1	0	93	98.9%
Total	195	3	2	200	97.5%

Trial 8

RPR Positive and FTA Negative Sera

Two sites (Public Heath Labs located in New York and Maryland) tested 25 frozen retrospective sera on the Captia Syphilis G that were RPR positive on initial screen and FTA negative on confirmation. The following table summarizes the results.

	Captia Syphilis Positive	Captia Syphilis Equivocal	Captia Syphilis Negative	% Negative
Site 1	0	0	25	100%
Site 2	0	2*	23	92%

*The two equivocals were negative with repeat testing.

Trial 9

Blood and Plasma Donor ScreeningApplication

a) **Comparison with the RPR test**

CAPTIA™ Syphilis-G was evaluated at 2 major US blood centres and a plasma centre, In comparison with the RPR test. A total of 9,323 donors were tested as plasma specimens by CAPTIA™ Syphilis-G and as serum specimens by the RPR test. 152 of the specimens were known reactive from previous serological testing which did not include the FTA-ABS test. 4,274 of these donors were additionally tested as serum specimens using CAPTIA™ Syphilis-G. Initially-reactive specimens were repeat tested in duplicate. Repeat-reactive specimens were confirmed using an FTA-ABS test. The following tables compare the CAPTIA™ and RPR before and after reconciliation of discordant results by the FTA test.

CAPTIA™ Tests Plasma Specimens: CAPTIA™ Syphilis-G, RPR and FTA-ABS Results

CAPTIA™ Syphilis-G	RPR	NUMBER		FTA-ABS	
		Initial	Repeat	Reactive	Non-reactive
R	R	131	130	127	3
R	N	89	72	57	15
E	R	3	3	3	0
E	N	22	13	8	5
N	R	23	23	1	22
N	N	9075	7	-	-
TOTALS		9323	248	196	45

Of 241 samples that were repeat reactive in either or both CAPTIA™ and RPR tests, 196 were FTA reactive, and 45 were FTA non-reactive.

CAPTIA™ (Tests Plasma Specimens)	RPR		Reactives and Discordants Reconciled by FTA-ABS	
	R	N	R	N
Reactive	133	85a	195	23
Non-reactive	23b	9082*	1	9140*
% Agreement	98.84 %		-	
Relative Sensitivity	133/158 = 85.26%		195/196 = 99.50 %	
Relative Specificity	9082/9187 = 99.01%		9104/9127 = 99.75 %	

* includes 9082 specimens which were CAPTIA™ and RPR concordant non-reactive and therefore not tested by FTA-ABS.

[a]65/85 were FTA reactive

[b]22/23 were FTA non-reactive. Equivocals were scored as reactive. In this study, there were 25 specimens (0.27%) initially equivocal by CAPTIA™ and 16 specimens (0.17%) repeat equivocal.

CAPTIA™ Tests Serum Samples: CAPTIA™ Syphilis-G, MHA-TP and FTA-ABS Results

CAPTIA™ Syphilis-G	MHA-TP	NUMBER		FTA-ABS	
		Initial	Repeat	Reactive	Non-reactive
R	R	81	83	83	0
R	E	1	0	0	0
R	N	2	2	2	0
E	R	3	6	6	0
E	E	5	1	1	0
E	N	2	2	2	0
N	R	17	3	1	2
N	E	14	1	0	1
N	N	2031	27	-	-
TOTALS		2156	125	95	3

Of 98 samples that were repeat reactive in either or both tests (CAPTIA™ and MHA-TP), 95 were FTA-ABS reactive, and 3 were FTA-ABS non-reactive.

CAPTIA™ (Tests Plasma Specimens)	MHA-TP		Reactives and Discordants Reconciled by FTA-ABS	
	R	N	R	N
Reactive	90	4[a]	94	0
Non-reactive	4[b]	2058*	1	2061*
% Agreement	99.83%		-	
Relative Sensitivity	90/94 = 95.74%		94/95 = 98.95%	
Relative Specificity	2058/2062 = 99.81%		2061/2061 = 100%	

* includes 2058 specimens which were CAPTIA™ and MHA-TP concordant non-reactive and therefore not tested by FTA-ABS.

[a] All reactive by FTA

[b] 3/4 non-reactive by FTA

Equivocals were scored as reactive. In this study, there were 10 specimens (0.46%) initially equivocal by CAPTIA™, and 9 specimens (0.42%) repeat equivocal.

c) **CAPTIA™ Syphilis-G: comparison of performance with plasma and serum specimens**

A total of 4,274 serum/plasma pairs were tested at 2 major US blood centres and a plasma centre using CAPTIA™ Syphilis-G. Results are summarized in the following table. 4,258 pairs (99.62%) gave concordant results on initial testing (equivocal scored as positive). Eleven (11) specimen pairs gave discordant results on repeat testing. Of these 11 repeat discordant pairs, the FTA-ABS test confirmed the plasma result for 6 pairs, and the serum results for the remaining 5 pairs.

dilutions. Types which can be racked in a configuration compatible with microtitration plates are recommended.

> Clean, disposable glass/plastic test tubes approximate capacities 5 mL and 10 mL.
> Range of standard, clean volumetric laboratory glassware consisting of, at least, 15 mL and 100 mL beakers, 1 mL, 5 mL, and 10 mL glass pipettes.
Absorbent paper towels.
> Automatic microtitration plate washer or laboratory wash bottle.
> Microtitration plate reader with 450 nm filter.
> Latex gloves, safety glasses and other appropriate protective garments.
> Biohazard infectious waste containers.
> Safety pipetting devices for 1 mL or larger pipettes.
> Timer.

Automatic, or Semi-automatic Processing

CAPTIA™ Syphilis-G may be used with a variety of automatic or semi-automatic processors/liquid handling systems. It is essential that any such system is qualified, before it is used routinely, by demonstrating that the CAPTIA™ Syphilis-G results obtained using the automatic processor are equivalent to those obtained for the same specimens using the manual test method. Subsequently the automatic processor should be periodically requalified.

3 *Storage and Stability*

All reagents should be stored at 2-8°C and should not be used beyond the expiration date on the label. Once opened, microtitration strips may be stored at 2-8°C until the expiration date on the label, provided that desiccated conditions are maintained. Unused strips should be returned to their original foil pouch along with the sachet of desiccant. Opened pouches should be securely resealed by folding over the open end and securing it with adhesive tape. If during storage, correct humidity conditions are not maintained, the desiccant will change colour from blue to pale pink. If this occurs, the microtitration strips should not be used.

The concentrated CAPTIA™ Wash Buffer contains no preservatives and, therefore, working-strength Wash Buffer should not be stored for longer than 2 weeks at 2-8°C. It is recommended that Wash Buffer be freshly diluted before each assay. If the working strength buffer becomes visibly cloudy or develops precipitate during the 2 weeks, do not use it.

Indications of Deterioration

CAPTIA™ Syphilis-G may be considered to have deteriorated if:

1 The kit fails to meet the required criteria for a valid test (see **6. Interpretation).**
2 Reagents becoming visibly cloudy or develop precipitate. Note: Concentrated wash buffer, when cold, normally develops crystalline precipitates which redissolve on heating at 37°C.
3 The CAPTIA™ TMB Chromogen (I %) turns blue immediately upon dilution. This is likely to be caused by chemical contamination of the CAPTIA™ Substrate Solution or the container used to prepare the dilute reagent.

4 *Warning and Precautions*

Safety

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The control sera in this kit contain 0.1% sodium azide as preservative. Sodium azide can react with lead and copper plumbing to form potentially explosive metal azides. Upon disposal, flush with a large volume of water to prevent azide build-up.

Caution: All blood products should be treated as potentially infectious. Source material from which kit control sera were derived was found negative when tested in accordance with current FDA recommendations. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.

The *Treponema pallidum* antigen has been inactivated during the production processes Nevertheless, treponemal antigen-coated microtitration wells should be handled using the normal precautions accorded to potentially infectious material.
The TMB Chromogen is dissolved in dimethyl sulphoxide which can irritate skin and mucous membranes. Any substrate solution coming into skin contact should be rinsed off with running water.
Sulphuric acid (2M) is corrosive. Avoid contact with skin and eyes. If splashing onto skin or eyes occurs, rinse the affected area with copious quantities of water and seek medical attention.

Procedural

1 This kit should be used in strict accordance with the instructions in the Package Insert.
2 CAPTIA™ enzyme immunoassay kits contain reagent systems which are optimized and balanced for each kit lot. Do not interchange reagents from kits with different lot numbers. Do not interchange vial caps or stoppers either within or between kits.
3 Do not use CAPTIA™ Syphilis-G kits after the expiration date printed on the outer

CAPTIA™ Tests Serum Specimens. CAPTIA™ Syphilis-G, RPR and FTA-ABS Results

CAPTIA™ Syphilis-G	RPR	NUMBER		FTA-ABS	
		Initial	Repeat	Reactive	Non-reactive
R	R	114	115	113	2
R	N	46	45	41	4
E	R	5	4	3	1
E	N	13	10	10	0
N	R	17	17	0	17
N	N	4079	4	-	-
TOTALS		4274	195	167	24

Of 191 samples that were repeat reactive in either or both tests (CAPTIA™ and RPR), 167 were FTA-ABS reactive and 24 were FTA-ABS non-reactive.

CAPTIA™ (Tests Plasma Specimens)	RPR		Reactives and Discordants Reconciled by FTA-ABS	
	R	N	R	N
Reactive	119	55[a]	167	7
Non-reactive	17[b]	4083*	-	4100*
% Agreement	98.32 %		-	
Relative Sensitivity	119/136 = 87.5%		167/167 = 100 %	
Relative Specificity	4083/4138 = 98.67%		4100/4107 = 99.83 %	

* includes 4083 specimens which were CAPTIA™ and RPR concordant non-reactive and therefore not tested by FTA-ABS
[a] 51/55 reactive by FTA
[b] All non-reactive by FTA
Equivocals were scored as reactive. In this study, there were 18 specimens (0.42%) initially equivocal by CAPTIA™ and 14 specimens (0.33%) repeat equivocal.

b) **Comparison with an automated MHA-TP** (haemagglutination) test

CAPTIA™ Syphilis-G was evaluated at two major US blood centres, in comparison with a commercially available automated MHA-TP system (PK-TP test). A total of 6,196 donors were tested as plasma specimens by CAPTIA™ Syphilis-G. 2,156 of these donors were additionally tested as serum specimens by CAPTIA™ Syphilis-G. The MHA-TP initial tests were performed with plasma specimens, and MHA-TP repeat tests were performed with serum specimens. Specimens which were repeat reactive in either test were confirmed using an FTA-ABS test.
The following tables summarize the results of all tests and compare CAPTIA™ and MHA-TP before and after reconciliation of discordant results by the FTA-ABS tests.

CAPTIA™ Tests Plasma Samples: CAPTIA™ Syphilis-G, MHA-TP and FTA-ABS Results

CAPTIA™ Syphilis-G	RPR	NUMBER		FTA-ABS	
		Initial	Repeat	Reactive	Non-reactive
R	R	85	91	91	0
R	E	6	0	0	0
R	N	16	19	9	10
E	R	2	1	1	0
E	E	1	1	1	0
E	N	15	7	2	5
N	R	49	4	1	3
N	E	24	1	0	1
N	N	5998	74	-	-
TOTALS		6196	198	105	19

Of 124 samples that were repeat reactive in either or both tests (CAPTIA™ and MHA-TP), 105, were FTA-ABS reactive and 19 were FTA-ABS non-reactive

CAPTIA™ (Tests Plasma Specimens)	MHA-TP		Reactives and Discordants Reconciled by FTA-ABS	
	R	N	R	N
Reactive	93	26[a]	104	15
Non-reactive	5[b]	6072*	1	6076*
% Agreement	99.32 %		-	
Relative Sensitivity	93/98 = 94.90%		104/105 = 99.05%	
Relative Specificity	6072/6098 = 99.57%		6076/6091 = 99.75%	

* includes 6072 specimens which were CAPTIA™ and MHA-TP concordant non-reactive and therefore not tested by FTA-ABS
[a] 11/26 FTA Reactive
[b] 4/5 FTA Non-Reactive
Equivocals were scored as reactive. In this study there were 18 specimens (0.29%) initially equivocal by CAPTIA™, and 9 specimens (0.15%) repeat equivocal.

CAPTIA- Syphilis-G		Number		FTA-ABS	
Serum	Plasma	Initial	Repeat	Reactive	Non-reactive
Reactive	Reactive	154	156	150	6
Reactive	Equivocal	4	3	3	
Reactive	Non-reactive	1	1	1	
Equivocal	Reactive	11	8	8	
Equivocal	Equivocal	4	6	5	
Equivocal	Non-reactive	4	1		1
Non-reactive	Reactive	5	7	4	3
Non-reactive	Equivocal	6	2	1	1
Non-reactive	Non-reactive	4085	6		
Total Tested		4274	189	183	
Total Reactive		189	183	172	

Specificity and Cross-reactivity

The following table summarizes CAPTIA™ Syphilis-G results from serum specimens taken from subjects with no known history or serological evidence of syphilis. This Group included serum specimens representing other disease states and/or characteristics known to cause false reactives in other serological tests for syphilis.

CATEGORY OF SPECIMEN	n	CAPTIA™ Syphilis-G Reactive*
Normal ante-natal	1002	0
HBsAg Reactive	68	1
ALT	125	2
Sera from HBV Vaccines	11	0
HIV 1/2 Antibody Reactive	32	0
HCV Antibody Reactive	134	2
HTLV 1 Antibody Reactive	34	0
Heterophile Antibody Glandular Fever) Reactive	17	0
Rheumatoid Factor R	33	1
Systemic Lupus E	22	1
Autoimmune/Connective Tissue Disease	18	0
Reagin Test False Reactive	66	0
Lyme's Disease	34	1
Genital Herpes	10	0
Acute Leptospirosis	10	0
Sera from Intravenous Drug	39	0
Hypergammaglobulinaemia	120	0
Miscellaneous**	18	0
Total Specimens	1690	
Total Representing Known Disease	888	
Total CAPTIA™ Reactive/FTA Non-Reactive	8	

* FTA Non-reactive

** Miscellaneous included 2 specimens from patients with arthritis and scleroderma, and one specimen each from patients with alzheimer; arthralgia; aspergillosis; coeliac disease; colitis C4 depressed; gout; immune complex infection; macroglobulinemia; myeloma (unspecified); myeloma IgA; myeloma IgG; myeloma light chain; nephrotic syndrome and acute renal failure.

Reproducibility

The reproducibility of CAPTIA™ Syphilis-G was evaluated concurrently at 3 separate US blood/plasma centres. Each centre tested 6 standard serum samples, replicated x 3 in each assay, on each of 5 days. The serum samples comprised: 2 x high titre reactive serum specimens; 2 x low titre (near the cut-off) reactive serum specimens and 2 x non-reactive serum specimens. Results are summarized in the following table:

	SAMPLE NUMBER					
PARAMETER	1	2	3	4	5	6
Intra-assay						
Mean antibody index: 15 runs: 3 sites	3.02	2.70	1.88	1.43	0.26	0.37
Range of within run %CV: 3 sites	2.95-4.38	3.20-5.40	3.23-6.47	3.01-8.01	3.76-4.44	1.79-5.81
Inter-assay						
Range of inter-assay %CV from 5 runs: 3 sites	5.87-11.21	5.52-10.23	4.68-9.53	8.34-13.47	6.56-11.21	7.40-12.81

The reproducibility of CAPTIA™ Syphilis-G was evaluated at two separate Public Health Labs. Each centre tested 6 standard serum samples, replicated x 3 in each assay, on each of 5 consecutive days. The same 6 samples were then replicated x 3 in each assay, separated by one week intervals for five weeks. The last two assays were each performed with different lots of kits. The serum samples comprised: 2 x high titre reactive serum specimens; 2 x low titre (near the cut-off) reactive serum specimens and 2 x non-reactive serum specimens. Results are summarized in the following table:

	SAMPLE NUMBER					
PARAMETER	1	2	3	4	5	6
Intra-assay						
Mean antibody index: 20 runs: 2 sites	3.60	4.89	1.48	1.41	0.15	0.13
Range of within run %CV: 2 sites	1.09-17.48	0.71-12.88	0.82-19.57	1.05-17.57	0.00-74.19	2.17-410.2
Inter-assay						
Range of inter-assay %CV from 20 runs: 2 sites	15.94-18.81	12.94-21.97	10.96-14.96	17.19-20.72	15.87-68.02	22.68-69.03

Sample #3 was equivocal 4/60 times
Sample #4 was equivocal 10/60 times
All other sera remained in the same status 60/60 times.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 9 2000

Mr. Wayne A. Kvetkosky
Corporate Director Regulatory Affairs
Trinity Biotech USA
PO Box 1059
2823 Girts Road
Jamestown, New York 14702-1059

Re: K001525
Trade Name: CAPTIA™ Syphilis-G
Regulatory Class: II
Product Code: LIP
Dated: August 30, 2000
Received: September 6, 2000

Dear Mr. Kvetkosky:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K001525
Device Name: CAPTIA™ Syphilis-G

Intended Use:
CAPTIA™ Syphilis *(T. pallidum*)-G is an enzyme immunoassay for the qualitative detection of IgG antibodies to *T. pallidum* in serum specimens, to be used in conjunction with non-treponemal testing to provide serological evidence of infection with *T. pallidum* (the agent of syphilis)

CAPTIA™ Syphilis *(T. pallidum*)-G is also intended for testing of serum or plasma specimens to screen blood and/or plasma donors to exclude a history of syphilis.

Note the following boxed warning appears directly below Intended Use in Package Insert.

Warning: A positive result is not useful for establishing a diagnosis of syphilis. In most situations, such a result may reflect a prior treated infection; a negative result can exclude a diagnosis of syphilis except for incubating or early primary disease.

Woody Dubois
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001525

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The Counter Use____
(Per 21 CFR 801.109) (Optional Format 1-2-96)